

REMARKS

Receipt of the Office Action mailed August 13, 2003 is acknowledged. Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the remarks that follow.

Claim 1 is currently being amended. This amendment is not a narrowing amendment related to patentability; rather, it is intended to be, and should be considered as, a correction of a typographical error.

Claim 2 is currently being amended. This amendment is not a narrowing amendment related to patentability; rather, it is intended to be, and should be considered as, a correction of a typographical error.

Claim 17 is currently being amended. This amendment is not a narrowing amendment related to patentability; rather, it is intended to be, and should be considered as, a clarification to the claim language. Applicant notes that the MPEP considers the term "characterized by" to be synonymous with "comprising." Manual of Patent Examining Procedure § 2111.03 (8th ed. 2003).

Claim 27 is currently being amended. This amendment is not a narrowing amendment related to patentability; rather, it is intended to be, and should be considered as, a clarification to the claim language.

Claim 29 is currently being amended. This amendment is not a narrowing amendment related to patentability; rather, it is intended to be, and should be considered as, a clarification to the claim language.

After amending the claims as set forth above, claims 1-9, 17, 18, and 26-38 are pending in this application. Claims 10-16 and 19-25 are withdrawn from consideration. There are four rejections of record. First, claims 4, 27, 29, and 31 stand rejected under 35 U.S.C. § 112, ¶ 2, as

being indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Second, claims 17 and 18 stand rejected under 35 U.S.C. § 102(b) as allegedly being unpatentable over Zabotto et al., United States Patent No. 4,661,343 (“Zabotto”). Third, claims 1-3, 5, 7-9, 17-18, 26-30, and 32-38 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laur et al., United States Patent No. 5,679,393 (“Laur”). Finally, claim 6 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laur in view of SU 1181171.

35 U.S.C. § 112, ¶ 2

The Examiner rejected claim 4, stating that it is unclear whether the amount recited is 100% or no more than 100%. Applicant respectfully traverses this rejection. Claim 1, from which claim 4 depends, requires that the pharmaceutical composition or the dietary supplement comprise at least 5% (w/w) of a triterpene fraction. Claim 4 further requires that the pharmaceutical composition or the dietary supplement comprise the triterpene fraction in a weight percentage of “at most 100% (w/w).” As such, claim 4 provides an upper limit to the amount of the triterpene fraction provided in claim 1, where the amount includes the endpoint of 100% (w/w). Applicant respectfully submits that the plain meaning of claim 4 is clear from the language of the claim.

The Examiner also rejected claims 27 and 29. The Examiner states that claims 27 and 29 further recite parkeol rendering them indefinite because parkeol’s main component is butyrospermol. Assuming that parkeol contains butyrospermol, applicant respectfully submits that claims 27 and 29 are not indefinite. Claim 1, from which claim 27 depends, claims a pharmaceutical composition or a dietary supplement that comprises at least 5% (w/w) of a triterpene fraction obtained from *Butyrospermum parkii*. The triterpene fraction in turn comprises at least 2% (w/w) butyrospermol. Claim 2, from which claim 29 depends, limits the amount of butyrospermol in the triterpene fraction disclosed in claim 1 to 10-40% (w/w). Dependent claims 27 and 29 further comprise a specified amount of parkeol, which Examiner contends contains butyrospermol. The addition of parkeol may increase the amount of

butyrospermol in the overall composition; however, applicant respectfully submits that this increase does not render the claims indefinite.

The Examiner further states that claim 27 is indefinite because the Examiner asserts that it is unclear whether the “at least 1%” language refers to only germanicol or to the entire Markush group. Without acquiescing in the rejection and without intending to abandon claimed subject matter but to expedite allowance, claim 27 has been amended. This amendment is not a narrowing amendment related to patentability; rather, it is intended to be, and should be considered as, a clarification of the claim language. As such, it respectfully suggested that the rejection is made moot by the amendment.

Finally, the Examiner rejected claim 31, stating that it is unclear whether the amount recited is at least 100% or more than 100%. Applicant respectfully traverses this rejection. Claim 1, from which claim 31 depends through claim 3, requires that the pharmaceutical composition or the dietary supplement comprise at least 5% (w/w) of a triterpene fraction. Claim 3 further requires that the pharmaceutical composition or the dietary supplement comprise a sterol fraction. Claim 31, in turn, further requires that the triterpene fraction together with the sterol fraction be in a weight percentage of “at most 100% (w/w).” As such, claim 31 provides an upper limit on the joint amount of the triterpene fraction and the sterol fraction provided in claim 3, where the amount includes the endpoint of 100% (w/w). Applicant respectfully submits that the plain meaning of claim 31 is clear from the language of the claim.

35 U.S.C. § 102(b) Rejection Over Zabotto

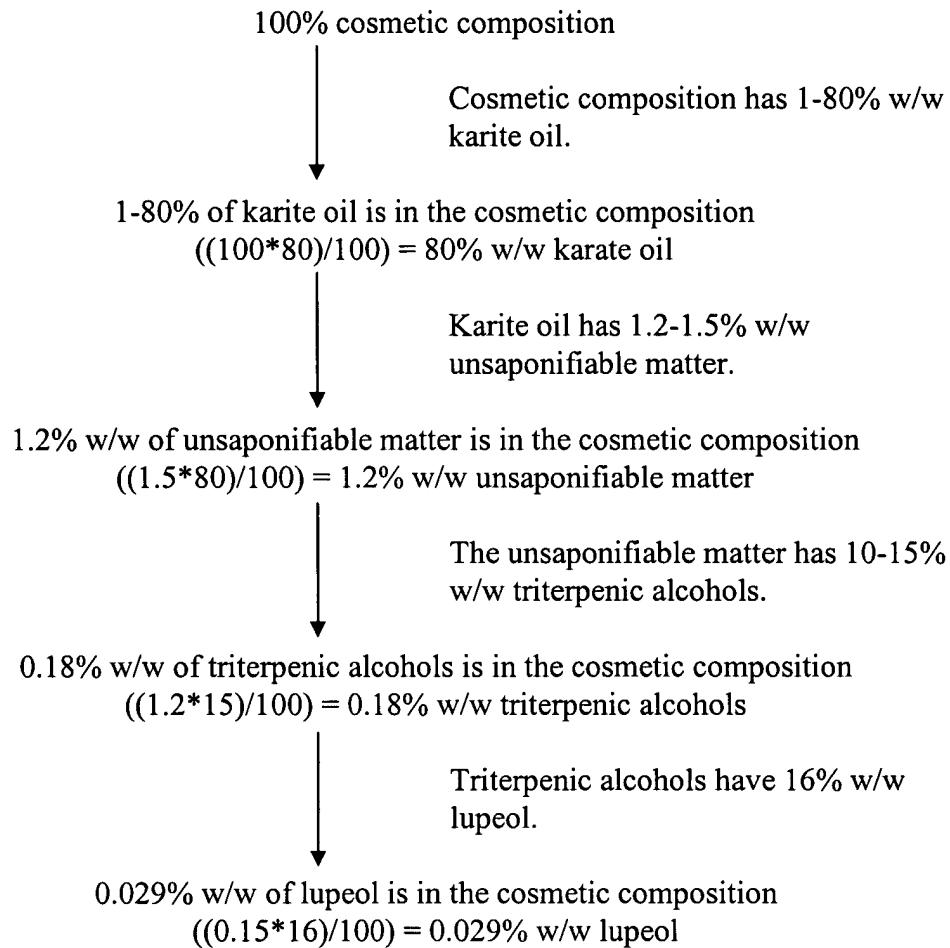
The Examiner rejected claims 17 and 18 under 35 U.S.C. § 102(b) as allegedly being unpatentable over Zabotto. The Examiner states that Zabotto discloses a cosmetic preparation containing karate oil from the tree Butyrospermum Parkii. The Examiner challenges the calculations made in the declaration, filed under 37 C.F.R. § 1.132 on August 20, 2002, and states that upon further consideration the declaration is insufficient to overcome Zabotto. The

Examiner alleges that the declarant erroneously divided by 100 during the course of his calculations.

In response, applicant respectfully submits that Zabotto does not disclose or teach all of the limitations of the presently claimed invention. Specifically, Zabotto does not disclose a composition comprising a triterpene fraction comprising the claimed components in the claimed amounts.

Applicant apologizes for any confusion the Examiner may have experienced regarding the declaration, filed under 37 C.F.R. § 1.132 on August 20, 2002. The declaration provides a comparison of the overall composition provided in Zabotto with the overall composition claimed in the above referenced application. It does not attempt to provide a comparison of the makeup of the karite oil in Zabotto with the triterpene fraction in the claimed invention. As a result, applicant respectfully submits that the calculations provided in the declaration are accurate for their intended purpose.

For example, the declaration computes the amount of lupeol in the total composition taught by Zabotto. The declaration acknowledges that Zabotto teaches a cosmetic composition having 1-80 % of karite oil. Within the karate oil, there is 1.2-1.5% w/w unsaponifiable matter. Within this unsaponifiable matter, 10-15% w/w is triterpenic alcohols. Within the triperpenic alcohol portion of the composition, lupeol makes up about 16% w/w. As a result, according to Zabotto et al, about 0. 029% of lupeol is in the cosmetic composition. The following flow chart describes the calculation provided in the declaration.



Likewise, the amount of α -amyrin (0.0006-0.0828% w/w), β -amyrin (0.0001-0.0180% w/w), and butyrospermol (0.0003-0.0468% w/w) can be calculated as disclosed in the declaration. Applicant respectfully submits that the amount of triterpenic alcohol should not be divided by the amount of total unsaponifiable matter, as the Examiner suggests, but rather the two values are multiplied during the course of this calculation. It is sincerely hoped that this flowchart will help clarify the calculations provided in the declaration.

In comparison, the compositions according to the present invention are at least 5% w/w triterpene fraction, at least 0.1% w/w lupeol, at least 0.1% w/w α -amyrin and/or β -amyrin, and at least 0.1% w/w butyrospermol. Zabotto does not disclose a composition having these amounts of

triterpene fraction, lupeol, α -amyrin and/or β -amyrin, or butyrospermol. As a result, applicant respectfully requests that the declaration is sufficient to overcome Zabotto.

35 U.S.C. § 103(a) Rejection Over Laur

The Examiner rejected claims 1-3, 5, 7-9, 17-18, 26-30, and 32-38 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laur. The Examiner refers to column 11, lines 40-51 of Laur as disclosing a pharmaceutical composition with shea butter fractions containing triterpene alcohols and sterols. The Examiner acknowledges that Laur does not disclose the instant amount of lupeol or butyrospermol of the total composition. However, the Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to look at the guidance of Laur and manipulate the amount of lupeol or butyrospermol desired in the composition. The Examiner argues that one would be motivated to do so since Laur teaches approximately 4.4% of butyrospermol and 3.9% of lupeol in one embodiment based upon 30% unsaponifiable material and the Examiner argues that Laur teaches utilization of up to 99% unsaponifiable material. Based on this, the Examiner argues that the amount of the individual components will change and Laur's teachings extend to the instant range of lupeol or butyrospermol in the total composition. The Examiner further states that the mere optimization of ranges of prior art conditions through routine experimentation does not support patentability of the subject matter encompassed by the prior art unless there is evidence of unexpected results.

Applicant respectfully submits that Laur does not disclose or teach all of the limitations of the presently claimed invention and, moreover, that the modification suggested by the Examiner would not have been obvious at the time the invention was made. The Examiner acknowledges that Laur does not disclose the instant amount of lupeol or butyrospermol of the total composition. Laur discloses fractions enriched with unsaponifiable materials. Yet, Laur does not disclose, nor would anyone of skill in the art have known, that the components presently recited -- lupeol, one or both of α -amyrin and β -amyrin, and butyrospermol -- are responsible for the desirable pharmaceutical properties that characterize applicants claimed invention. In addition, Laur does not disclose and would not have suggested that providing a composition

enriched in these components increases the therapeutic effect. Laur also does not evidence a motivation to have modified the amounts as recited in the instant invention.

Applicant submits that he is not merely optimizing ranges in the prior art; rather, by using a unique extraction procedure, applicant identified a unique composition that exhibits unexpected properties relative to the prior art. Examples 1 and 2 in the specification illustrates these unexpected properties. In Example 1, the test composition according to the invention containing 26% Butyrospermum-triterpenes exhibited statistically significant inhibition of arthritis compared with no treatment. In Example 2, the test compositions according to the invention containing 10-30% Butyrospermum-triterpenes dose-dependently inhibit the inflammation of mouse skin, while the shea butter control has no anti-inflammatory effect. This is surprising because such effects are not obtainable with lower levels of Butyrospermum-triterpenes that, through the use of shea butter as an emollient, have been used in topical pharmaceutical or cosmetic products.

Applicant respectfully submits that the Examiner's statement that Laur teaches utilization of 99% *unsaponifiable material* is inaccurate. Laur teaches utilization of at most 99% of a mixture of *unsaponifiable fractions*. (See col. 5, ll. 44-46) Laur further teaches that this mixture of unsaponifiable fractions contains 18-50% of unsaponifiable compounds. (See col. 5, ll. 40-41) As a result, the maximum amount of unsaponifiable compounds disclosed by Laur is 49.5%, not 99% as the Examiner suggests. The calculation presented by applicant was based on example 7 of Laur, which discloses a composition having 1-60% of a shea butter fraction with unsaponifiable materials in an undisclosed amount. The calculation concluded that one embodiment of this composition would have 30% unsaponifiable materials ($60*50/100$). The Examiner's correction is duly noted, but does not render this invention obvious for the reasons discussed above.

35 U.S.C. § 103(a) Rejection Over Laur in View of SU 1181171

Claim 6 relies on claim 1. If the Examiner determines that claim 1 is not obvious, it is respectfully requested that claim 6 likewise be deemed not obvious.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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